**Office of the Director**
**Division of Practice Activities**
**Stanley Zinberg, MD, MS, FACOG**
**Telephone (202) 863-2500**
**Fax (202) 484-3993**

***MEMORANDUM***

TO: FDA Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee

FROM: Stanley Zinberg, MD, MS, FACOG SZ
Director of Practice Activities

DATE: October 6, 1997

SUBJECT: HUAM

The reduction of preterm births due to spontaneous preterm labor and delivery is of great importance and a top priority of the ACOG. We have supported assessment and education of providers and our patients via our educational and committee publications. We have in place a mechanism and system to regularly and prospectively review the efficacy and safety of all current and newly recommended strategies of interventions directed toward the reduction of preterm birth. However, ACOG has long been equally concerned with the problem of provider usage and vendor marketing of unproven interventions and strategies. Unwarranted implementation of such interventions is wasteful of resources that may better be directed toward proven strategies to improve perinatal outcomes and may also be harmful in terms of maternal and/or fetal/neonatal safety effects.

Specifically, in regard to HUAM, ACOG's Committee on Obstetric Practice has most recently reported on this topic in May 1996 (Committee Opinion #172 Home Uterine Activity Monitoring). We concluded that well-designed, prospective, randomized clinical studies of sufficient power are needed to establish the benefit, if any, of HUAM for the prevention of preterm delivery or for the prevention of associated adverse neonatal outcomes. Our conclusion was based on a comprehensive literature review to May 1996 as well as an ACOG funded independent outside meta-analysis review of the available literature on this subject. Since May 1996 no further randomized trial of sufficient power has been reported to alter our conclusion regarding any beneficial effects of the intervention/strategy to significantly reduce the incidence of preterm births. However, we believe that the recent Dyson et al (Divisions of Maternal-Fetal Medicine, Departments of Obstetrics and Gynecology, Kaiser Permanente Medical Care Program, Northern California Region) publication on the utility of HUAM is a landmark and definitive report on this subject. These authors randomized 2,422 women at risk for preterm labor to receive education and either weekly nursing contact, daily nursing contact or daily nursing contact with home uterine activity monitoring. The primary study endpoint was the incidence of preterm birth < 35 weeks gestation and secondary endpoints included cervical status of the diagnosis of preterm labor and selected measures of neonatal morbidity.

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